

**Cholestech**  
**LDX<sup>®</sup>**

## System User Manual



CHOLESTECH 



# System User Manual

## Read Me First

Congratulations on the purchase of your Cholestech LDX System. Please take a few minutes to examine the contents of your package to be sure that nothing has been damaged in shipment. It is critical to fill out the warranty card enclosed, to ensure a record of your one-year warranty.

Be sure to read the instructions in this user manual before operating the Cholestech LDX. If you have any questions now or in the future, please contact Cholestech Technical Service at 1.800.733.0404 or 1.510.732.7200, by fax at 1.510.732.7227, or via e-mail at [ctec\\_support@cholestechn.com](mailto:ctec_support@cholestechn.com).

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# Warranty and Service

Cholestech guarantees that each Analyzer will be in good working order on the day it is installed and that it will conform to Cholestech's specifications. Cholestech or its agent will provide service to keep or restore each Analyzer to good working order for one year at no additional charge to the purchaser. An extended warranty may be purchased if desired. Warranty service provided under this agreement does not assure uninterrupted operation of the Analyzer. The Service provided by Cholestech under this agreement does not include:

1. Repair or replacement made necessary because of the use of the equipment for other than the ordinary use for which it was designed, as stated in Cholestech publications.
2. Repair or replacement made necessary because of accident; disaster (which includes, but is not limited to, fire, flood, earthquake, water, wind and lightning); transportation; neglect or misuse; or alterations (which include, but are not limited to, any deviation from Cholestech's physical, mechanical or electrical machine design).

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## *Introduction*

The Cholestech LDX is a small, portable analyzer and test cassette system. It is easy to use, and gives fast and reliable results. To run a test, just add a sample to the cassette and place it into the Analyzer. In a few minutes the results will appear on the screen.

The Cholestech LDX System is for *in vitro* diagnostic use only. This manual contains all the information you need to operate and care for the Cholestech LDX Analyzer. Please read this entire manual before you use the Analyzer.

### **Technical and Customer Service**

Cholestech Corporation will provide every customer with the technical support and training needed to properly use the Cholestech LDX System. We maintain a staff of qualified Technical Service Representatives available 24 hours a day, seven days a week.

For current ordering information, or any other customer service-related questions, our Customer Service department is available from 6:00 AM to 5:00 PM Pacific time, Monday through Friday.

*Please feel free to contact us at:*

Cholestech Corporation  
3347 Investment Blvd.  
Hayward, CA 94545 U.S.A.  
Tel 1.800.733.0404  
Fax 1.510.732.7227  
ctec\_support@cholesteck.com

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## Examining Your Package Contents

When you receive your Cholestech LDX, open the shipping box and check the contents against the packing list. Please save the shipping box for reuse if you plan to send the Cholestech LDX Analyzer and supplies to other sites. The Cholestech LDX System Includes:

- Cholestech LDX Analyzer
  - Power Supply
  - Optics Check Cassette
  - User Manual
  - Procedure Manual CD
  - Warranty Card
  - Accessory Tray
  - Capillary Tubes
  - Capillary Plungers
  - Lancets
  - MiniPet Pipettes
  - Pipette Tips
  - Printer and Cable Assembly
  - Training Video
-

A carrying case is available as an optional accessory.  
(The carrying case is not intended for shipping the Cholestech LDX Analyzer.)

In addition to these supplies, you may need the following materials that are not provided with your Cholestech LDX Analyzer:

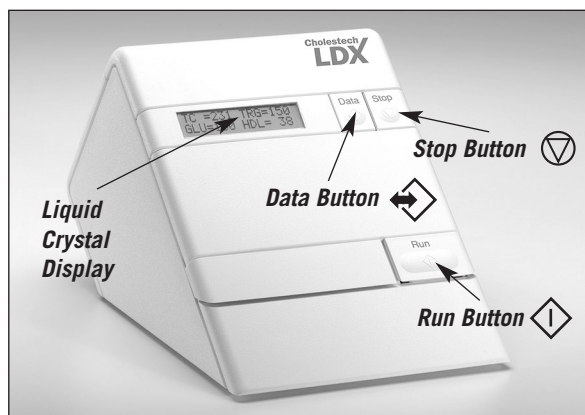
- Cholestech LDX Test Cassettes
- Cholestech Level 1 and 2 Controls
- Biohazardous waste containers
- Alcohol swabs
- Gloves
- Gauze sponges
- Vacuum collection tubes, needles and tube holders if the sample is to be collected by venipuncture.

**IMPORTANT: If you haven't filled out the warranty card, please do so now, and mail it to Cholestech, or you can do so online at [www.cholesteck.com/register/](http://www.cholesteck.com/register/).**

Cholestech Corporation  
3347 Investment Blvd.  
Hayward, CA 94545 U.S.A.

## How the Cholestech LDX Works

The Cholestech LDX System uses reflectance photometry (the amount of light reflected from a solid surface) to measure the amount of substances in blood. The Analyzer measures color changes of the four reagent pads. The amount of color formed is converted by the Analyzer to a concentration and the results are shown on the liquid crystal display (LCD) screen.



## THE ANALYZER

The Cholestech LDX Analyzer has a 32-character display screen and three buttons that control all the steps needed for operation. The three buttons are labeled **RUN**, **DATA** and **STOP**.

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***RUN:***

1. Opens the cassette drawer or activates the Analyzer.
2. Starts a test. Press the **RUN** button after a cassette is placed in the drawer to start a test.
3. Allows you to enter information into the Risk Assessment Program and change settings in the Configuration Menu when used with the **DATA** button.

***DATA:***

1. Allows you to review the results from the last cassette tested.
2. Allows you to enter information into the Risk Assessment Program.
3. Allows you to change settings in the Configuration Menu.

***STOP:***

1. Stops a test.
2. Closes the drawer.
3. Allows you to enter and exit the Configuration Menu of the Analyzer.

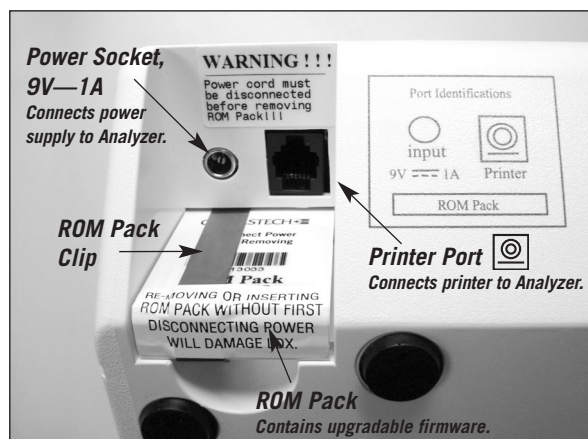
The drawer will close and the screen will go blank after four minutes without use.

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**INTRODUCTION***Cholestech LDX System User Manual*

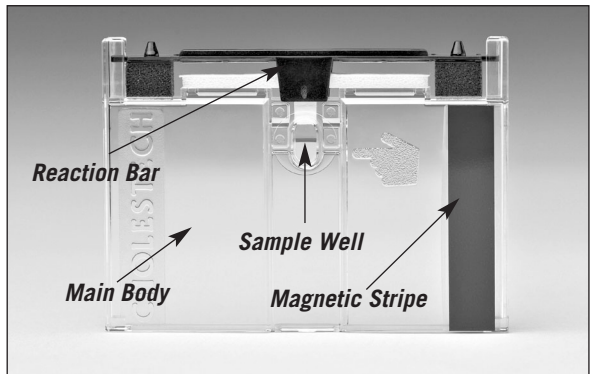
In the back of the Analyzer are two ports: a circular port for the power supply and a rectangular port used for connecting the Analyzer to a printer. There is also a ROM pack that contains upgradable firmware. The power supply provides the Analyzer with 9 volts DC at 1 amp. A country-specific power supply is included.

**IMPORTANT:** The Cholestech LDX contains a battery that cannot be replaced by the user. Battery life is greatly reduced if the Analyzer is left unplugged. To conserve this battery, we recommend plugging in the Analyzer when not in use.

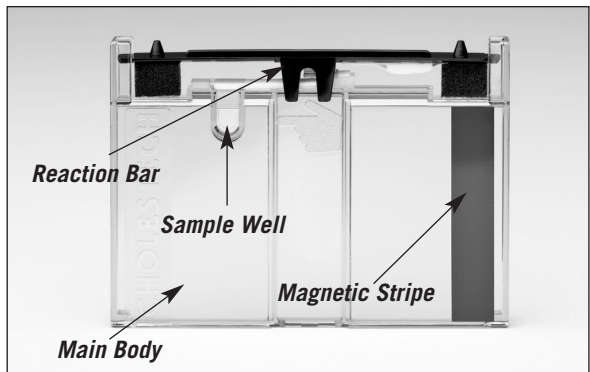


## THE TEST CASSETTES

Cassette Type 1 is used for lipids, ALT, AST, and glucose. Cassette Type 2 is used for hs-CRP only. Each test cassette has two parts: the main body and the reaction bar. The main body contains a sample well where the blood sample is dispensed, and a brown magnetic stripe. The magnetic stripe contains the test names, instructions to the Analyzer for running the tests on the cassette, and calibration information for converting the color reading to analyte concentration.



Cassette Type 1



Cassette Type 2

## Getting Started

Use your Cholestech LDX System in a location that has:

- Room temperature 68–87°F (20–31°C)
  - A stable work surface (NO centrifuges)
  - No direct heat (oven or room heater)
  - No bright light (sunlight or spotlight)
1. Check that the ROM pack is completely inserted and the clip is in place.
  2. Insert the power supply plug into the round socket in the back of the Analyzer.
  3. Plug the power supply into the wall outlet.

**IMPORTANT: Do not remove the ROM pack while the Analyzer is plugged in. The Analyzer will lose its optical calibration and will no longer function.**

The following messages will appear on the screen:

Testing memory

Selftest  
running.

Selftest OK

### FOR MULTI-LANGUAGES ONLY.

**Note:** The translations that show on the LDX screen do not include the language accents due to hardware limitations of the LDX display.

**IMPORTANT: If these messages do not appear, check the power connections. If these messages still do not appear, or if the screen reads:**

Calibration Fail  
...Call Tech Serv

Call Cholestech Technical Service.

If the Analyzer is not yet at the proper operating temperature (warmed up), the screen will display:

Initial Warm-Up  
\*\*\*\*\*

## Setting the Configuration Menu

Before using your Cholestech LDX Analyzer, you should enter the Configuration Menu and set it to best meet your needs. The following items can be customized:

|                  |   |                    |
|------------------|---|--------------------|
| Language         | English, Italian, Spanish, German, French   |                    |
| Units            | mg/dL=milligrams per deciliter<br>mmol/L=millimoles per liter<br><br><b>Note:</b> U/L (units per liter) and mg/L (milligrams per liter) will be reported when the Configuration Menu is set for either UNITS=mg/dL or UNITS=mmol/L. |                    |
| Sample           | Whole B.=Venous or capillary whole blood<br>Serum=Serum or plasma, and control, calibration verification or proficiency testing material  |                    |
| Printer          | On=printer function turned on<br>Off=printer function turned off  |                    |
| Number of Copies | 1=1 printed label<br>3=3 printed labels   | 2=2 printed labels |
| Risk             | CHD Risk=Framingham Risk on<br>Off=Risk assessment option is turned off   |                    |
| Date             | Day of week, month, day, and year=English<br>Day of week, day, month, and year=Alternate language settings  |                    |
| Time             | Hour, minutes, seconds, AM/PM=English<br>Hour, minutes, seconds, (24 hour)=Alternate language settings  |                    |

1. To enter the Configuration Menu, press the **STOP** button and hold down until the firmware version appears.
2. The first item in the Configuration Menu then will be displayed.
3. The **DATA** button allows you to select choices for each of the menu items in the Configuration Menu. The **RUN** button enters your choice and advances you to the next menu item.
4. You can press **STOP** at any time to exit the Configuration Menu.

Example: The screen will display:

```
Config menu
UNITS=mg/dL
```

If you wish to change the units displayed, press the **DATA** button to change to:

```
Config menu
UNITS=mmol/L
```

When the desired choice is displayed, press the **RUN** button to enter the choice and to advance to the next item.

## Configuration Menu Flowchart

The Analyzer allows you to customize function settings in the Configuration Menu.

### LCD Display:

Firmware Version

Config menu  
Lang=English

Config menu  
UNITS=mg/dL

Config menu  
SAMPLE=Whole B.

Config menu  
Printer on

Config menu  
num copies? 1

Config menu  
Risk=CHD Risk

Config menu  
Tue Aug 16, 2005

Config menu  
TIME=9:08:29 AM

### To Access the Configuration Menu:

• Press **STOP** on the Analyzer and hold until the FIRMWARE VERSION appears. The next display will appear *automatically*.

• Press **DATA** to select LANGUAGE CHOICES:  
– *English, Italiano, Español, Deutsch, or Francais*  
• Press **RUN** to advance to the next option.

• Press **DATA** to select UNITS: *mg/dL or mmol/L*  
• Press **RUN** to continue.

**Note:** U/L and mg/L will be reported when the Configuration Menu is set for either UNITS=mg/dL or UNITS=mmol/L.

• Press **DATA** to select SAMPLE TYPE:  
– *Whole B.* (Set for venous or capillary whole blood samples.) *or*  
– *Serum* (Proficiency test material, calibration verification material.)  
• Press **RUN** to continue.

**Note:** Check control material product insert to determine correct sample setting when running controls.

• Press **DATA** to select PRINTER OPTIONS:  
– *On* (Printer function turned on.) *or*  
– *Off* (Printer function turned off.)  
• Press **RUN** to continue.

• Press **DATA** to select COPY OPTIONS:  
– *1* (One copy of test results will print.) *or*  
– *2* (Two copies of test results will print.) *or*  
– *3* (Three copies of test results will print.)  
• Press **RUN** to continue.

• Press **DATA** to select RISK ASSESSMENT OPTIONS:  
– (Select this option if you want to perform  
Coronary Heart Disease Risk Assessment.) *or*  
– *Off* (CHD Risk Assessment function is turned off.)  
• Press **RUN** to continue.

**Note:** If the Framingham option is selected, the printer will not print test results until the assessment is complete.

• Press **DATA** to select DAY OF WEEK: *Mon–Sun.*  
• Press **RUN** to continue.  
• Press **DATA** to select MONTH: *Jan–Dec.*  
• Press **RUN** to continue.  
• Press **DATA** to select DAY: *1–31.*  
• Press **RUN** to continue.  
• Press **DATA** to select YEAR: *1999–2030.*  
• Press **RUN** to continue.

• Press **DATA** to select HOUR: *1–12.*  
• Press **RUN** to continue.  
• Press **DATA** to select MINUTES/SECONDS: *0–59.*  
• Press **RUN** to exit Configuration Menu.

**Note:** When "English" is the selected language, AM or PM is displayed. When any other language setting is selected, the hours are shown in 24-hour format from 00:00 to 24:00 hours.

**Note:** Press **STOP** at any time to exit the Configuration Menu.

## Cholestech LDX Optics Check

A Cholestech LDX Optics Check Cassette initially is supplied with the Analyzer. It should be used to check the optical system of the Analyzer. Store the Cholestech LDX Optics Check Cassette at room temperature in the case provided. Do not touch the reaction bar or allow it to become wet, dirty or scratched. Do not use a damaged or expired Cholestech LDX Optics Check Cassette.

Run the Cholestech LDX Optics Check Cassette:

- Once each day before patient samples are tested.
- After the Cholestech LDX System has been moved or serviced.

## Optics Check Cassette Test Procedure

Do not use a Cholestech LDX Optics Check Cassette that has become damaged or altered in any way.

**IMPORTANT: Do not place any blood sample on the cassette.**

1. Press the **RUN** button. After verifying the Selftest OK message, the drawer will open. This message will appear:

Load cassette  
and press RUN.

2. Place the Optics Check Cassette into the cassette drawer.
3. Press the **RUN** button again and the Analyzer will automatically perform the optics check. The words Optics Check and four numbers will appear on the screen, one for each optical channel in the Analyzer.

Optics Check  
ch#1-ch#2-ch#3-ch#4



4. Check to see that the numbers are within the acceptable range (80–105), which is printed on the Optics Check Cassette. Record the results in the Optics Check Log each day.
5. If the numbers are outside the printed range, this message will appear.

```
Optics Test Fail  
ch#1-ch#2-ch#3-ch#4
```

6. If an expired Optics Check Cassette is used, this message will appear.

```
Expired Cassette  
ch#1-ch#2-ch#3-ch#4
```

7. If an expired Optics Check Cassette is used, and then a test cassette is used, this message will appear following the test results.

```
Expired  
Optics Cassette
```

---

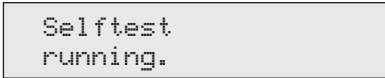
# Testing Procedure

## Running a Test

For more information, see the test cassette product inserts. The Quick Reference Guide gives a brief summary of the procedure.

**IMPORTANT: Gloves should be worn whenever working with samples that are potentially biohazardous.**

1. If the cassettes have been refrigerated, allow them to come to room temperature (at least 10 minutes) before opening.
2. Make sure the Analyzer is plugged in and has warmed up.
3. Remove the cassette from its pouch. Hold the cassette by the short sides *only*. **Do not touch the black bar or the brown magnetic stripe.** Place the cassette on a flat surface.
4. Press **RUN**. The Analyzer will do a selftest, and the screen will display:

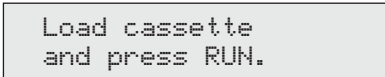


```
Selftest  
running.
```



```
Selftest OK
```

5. The cassette drawer will open, and the screen will display:



```
Load cassette  
and press RUN.
```

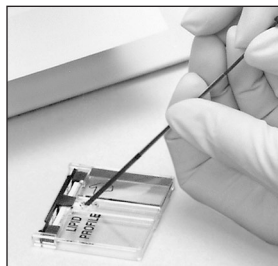
6. Depending on the sample type, use the Cholestech LDX Capillary Tube (fingerstick) or a MiniPet Pipette (venous or control material) to place sample into the test cassette sample well. (See “Performing a Fingerstick” and “Using Your MiniPet Pipettes,” pages 19–22, for additional information.)

The **35 µL** MiniPet Pipette is used for lipids, ALT, AST, and glucose to pipet serum, plasma and whole blood samples and controls, calibration verification and proficiency testing materials.

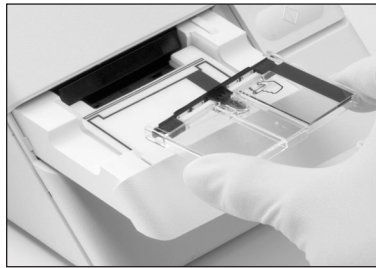
The **40 µL** MiniPet Pipette is used for **hs-CRP** to pipet serum and plasma samples and controls, calibration verification and proficiency testing materials.

The **50 µL** MiniPet Pipette is used for **whole blood samples** for hs-CRP.

**IMPORTANT: A fingerstick sample must be applied within five (5) minutes after collection or the blood will clot.**



7. Keep the cassette level after the sample has been applied. **WARNING: Allowing the sample to sit in the cassette will cause inaccurate results.** Immediately place the cassette into the drawer of the Analyzer. The black reaction bar must face toward the Analyzer. The brown magnetic stripe must be on the right.



8. **DO NOT PUSH IN TRAY.** Press **RUN**. The drawer will close. During the test, the screen will display:

```
[Test Name(s)]  
Running*****
```

9. Put everything that came into contact with the blood samples or control, calibration verification or proficiency testing material into a biohazardous waste container.
10. When the test is complete, the Analyzer will beep, and the screen will display:

```
[Test Name(s)]=###  
Warnings
```

11. Press **DATA** to view the calculated results.

12. When the results are outside the measuring range of the test, the screen will display:

[Test Name] > ###

or

[Test Name] < ###

13. If there is a problem with the test, a message will appear on the screen. (See the *Troubleshooting & Maintenance* section, pages 32–35, for further instructions.)
14. When the drawer opens, remove the cassette, and put it in a biohazardous waste container. Leave the Analyzer drawer empty when not in use.
15. Record the results on the appropriate form.
16. To run another test cassette, press **RUN** once.

Load cassette  
and press RUN.

17. Repeat step 3, and steps 6 through 15.
18. Otherwise, after four minutes a beep will sound and the screen will display:

System timeout  
RUN to continue

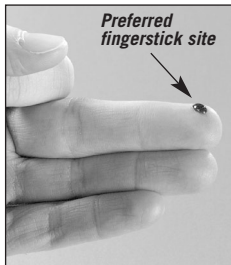
**IMPORTANT: If the RUN button is not pushed within 15 seconds, the drawer will close and the screen will go blank.**

19. If necessary, press the **DATA** button to view the results from the last cassette tested.

## Performing a Fingertick

**IMPORTANT: A warm hand and good blood flow from the puncture site are essential to collect a good capillary sample. Also, Cholestech supplies two different capillary tubes: 35  $\mu$ L and 50  $\mu$ L. The 50  $\mu$ L tube must be used with the hs-CRP cassette. The 35  $\mu$ L tube is used with all other test cassettes.**

1. The patient should sit quietly for five minutes before the blood sample is collected.
2. Put a capillary plunger into the end of a Cholestech capillary tube with the red mark. Set it aside.
3. Choose a spot **on the side of one of the center fingers** of either hand. To help increase blood flow, the fingers and hands should be warm to the touch. To warm the hand, you can:



- a. Wash the patient's hand with warm water, or...
  - b. Apply a warm (not hot) compress to the hand for several minutes, or...
  - c. Gently massage the finger from the base to the tip several times to bring the blood to the fingertip.
4. Clean the site with an alcohol swab. **Dry thoroughly with a gauze pad before pricking the finger.**
  5. Firmly prick the selected site with a lancet.



6. Squeeze the finger gently to obtain a large drop of blood. Wipe away this first drop of blood, as it may contain tissue fluid.



7. Squeeze the finger gently again while holding it downward until a second large drop of blood forms. **Do not milk the finger.** The puncture should provide a free-flowing drop of blood.
8. Hold the capillary tube horizontally by the end with the plunger. Touch it to the drop of blood without touching the skin. The tube will fill by capillary action up to the black mark. **Do not collect air bubbles.** If it is necessary to collect another drop of blood, wipe the finger with gauze then massage again from base to tip until a large drop of blood forms.



9. Fill the capillary tube within 10 seconds.
10. Wipe off any excess blood from the finger and have the patient apply pressure to the puncture until the bleeding stops.

**Follow these suggestions to help you consistently perform good fingersticks:**

| Suggestion   | Reason  |
|--|---|
| Perform a deep and firm puncture.  | An adequate puncture is crucial to obtaining a free-flowing drop of blood.          |
| Keep the patient's hand below the level of his or her heart.               | This will improve the blood flow.   |
| Hold the capillary tube at a slight descending angle to the drop of blood. | This will make the capillary tube fill faster.                                      |
| Fill the capillary in less than 10 seconds.                                | This will ensure proper mixing of blood and anticoagulant, which prevents clotting. |
| Dispense blood from the capillary tube in less than five minutes.          | After five minutes, the blood may begin to clot in the capillary tube.              |
| If blood stops flowing, wipe finger firmly with gauze.                     | You can improve blood flow by reopening the puncture.                               |

**WARNING:** Squeezing the finger excessively may cause inaccurate test results.



## Using Your MiniPet™ Pipettes

*(Refer to page 16 for proper pipette selection.)*

Use this procedure to apply a sample of venous **serum, plasma or whole blood, or control, calibration verification or proficiency testing material** to the cassette. (See cassette-specific package insert for volume amount.)

1. Firmly attach the pipette tip to the end of the MiniPet pipette. Use a new tip for each sample.
2. To fill the pipette, push the plunger down as far as you can. Place the pipette tip into the sample and **slowly** release the plunger. Confirm that no air bubbles are in the pipette tip.
3. Place the pipette tip into the cassette sample well. Dispense the sample by pressing the plunger down. **Move the pipette tip out of the sample well before releasing the plunger again.**
4. Remove the pipette tip and put it into a biohazardous waste container.

**IMPORTANT:** If the plunger is released before the pipette tip is removed from the sample well, the sample may be drawn back into the pipette tip.

**IMPORTANT:** Keep the cassette level at all times after applying the sample.

*For additional information about proper handling of blood specimens, see the product insert for the test cassette you are using.*

# Quality Control

Quality control refers to the testing done to show that a system is working properly and giving dependable results.

## Choosing Quality Control Materials

The quality control materials (controls) sold by Cholestech are those recommended for use with the Cholestech LDX System.

If you decide to use other controls, you will need to determine their precision and expected ranges on the Cholestech LDX System.

## Handling Controls

- Read the product insert that comes with each box of controls to find out how to use and store them.
- Check the expiration date before using. **Do not use expired control material.**
- Mix controls well before use. Hold the top and bottom of the bottle and gently turn it upside down seven to eight times to mix.
- Check the control assay sheet for the correct sample setting for running controls.
- Verify that the lot number on the control vial and the assay sheet are the same.

## External Quality Control

External controls also must be used to demonstrate that the reagents and assay procedure perform properly.

Level 1 and Level 2 Controls are available from Cholestech. Controls must be tested:

- With each new shipment of cassettes (even if cassettes are from the same lot previously received).
- With each new lot of cassettes.
- As otherwise required by your laboratory's standard quality control procedures.

- If you are not running the Cholestech LDX under CLIA-waived status, or if your local or state regulations require more frequent testing of quality control material, then quality control must be performed in compliance with those regulations.

Good Laboratory Practice principles suggest that external controls must be run whenever the laboratory director has any question about test system integrity or operator technique (e.g., when reagents may have been stored or handled in a way that can degrade their performance or when operators have not performed a particular test in recent weeks).

If the controls do not perform as expected, repeat the test or contact Cholestech Technical Service before testing patient samples.

**The quality control results should be in range before testing patient samples. See page 25 of this manual if they are not.**

**Please call Cholestech Technical Service at 1.800.733.0404 if you have any questions about quality control.**

### **Control Range**

Results for Cholestech controls should be within the ranges included with the control.

### **Results Within Control Range**

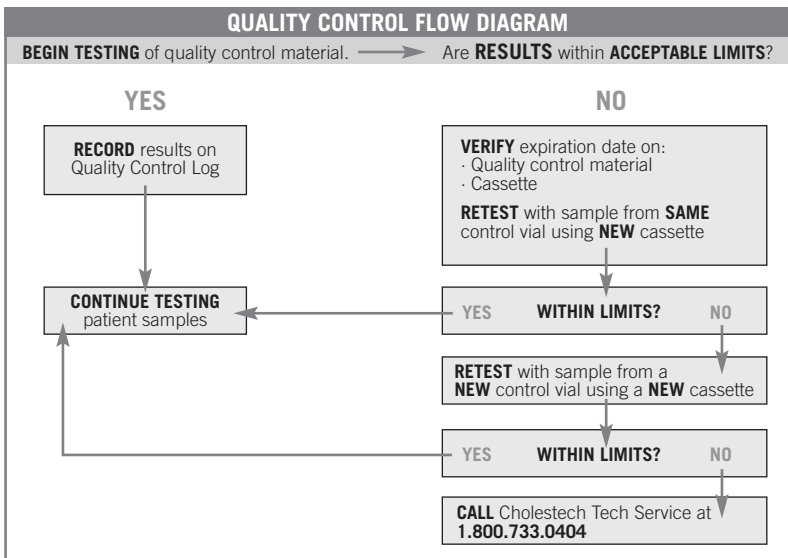
If results for all analytes are within the expected ranges, patient samples may be tested and the results reported.

---

## Results Outside the Control Range

If results of one or both levels of control tested are outside the established ranges:

1. Verify that the lot number on the control vial and the assay sheet are the same.
2. Check the expiration date for the test cassette and quality control materials. Discard expired products.
3. Retest the control level that is out of range using a new sample from the same control vial. Pay careful attention to possible errors in technique.
  - a. If the control is within acceptable limits, patient samples may be tested and results reported.
  - b. If the control is outside the acceptable limits, retest with a sample of control from a new vial.
    - If results are in range, continue testing patient samples.
    - If the control is still outside the acceptable limits, contact Cholestech Corporation Technical Service. Do not use the Analyzer for testing patient samples until the problem is resolved.



---

## *Moderately Complex Tests*

If you are running a test cassette that is classified as moderately complex under CLIA, note the following:

### **Sample Type**

Any sample type may be used—fingerstick (capillary) or venous whole blood, serum or plasma. When running serum or plasma, change the Sample Type in the Configuration Menu to “Serum.”

### **Quality Control Recommendations**

Quality control materials should be tested:

- On each new shipment of cassettes.
- On each lot of cassettes received.
- If you think cassettes may not have been stored properly.
- Each day that patient samples are tested.

### **Optics Check Cassette**

The Optics Check Cassette should be run each day that patient samples are tested.

### **Proficiency Testing**

Proficiency testing is required when testing under CLIA moderately complex status. Call Cholestech Technical Service for more information on proficiency testing agencies.

### **Calibration Verification**

Call Cholestech Technical Service, 1.800.733.0404, for recommended Calibration Verification material.

**IMPORTANT: Read the package insert for the test cassettes you are using for any special instructions.**

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# Risk Assessment

## Coronary Heart Disease (CHD) Risk Assessment Program

The Cholestech LDX CHD Risk Assessment Program is based on data from the *Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults*.<sup>\*</sup> The relationship between these risk factors and CHD is derived from the Framingham Study.

The Framingham Study documents and tracks the effects of variables involved in the development of CHD. The age range for the study is 20–79 years, and includes both men and women.

The risk assessment program may be used with any test cassette that provides results for both total cholesterol and HDL cholesterol. This program calculates the percentage risk of developing coronary heart disease (CHD) over 10 years based on test results and the following risk factors:

- Sex (male, female)
- Smoking (yes, no)
- Age (20–79)
- SBP (systolic blood pressure)
- SBP has been treated or not treated
- The risk calculation is valid for persons 20–79 years of age who are currently free of CHD.

Although the effects of family medical history, obesity and exercise may be relevant, they were not included as separate risk factors in the risk assessment developed by the Framingham Study.

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<sup>\*</sup> Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). *JAMA* 2001; 285:2486-97.

## Performing a CHD Risk Assessment

See “Setting the Configuration Menu” (pages 10–11).  
When “Risk=” appears, select CHD Risk.

1. After a cassette is run that includes total cholesterol and HDL results, press the **DATA** button until Risk Assessment Program screen appears. The screen will display:

```
Risk?  
RUN=yes, STOP=no
```

2. Press the **RUN** button to enter the Risk Assessment patient information collection screens. These screens will look like this:

```
CHD risk data  
Smoke=no
```

3. Press the **DATA** button to select patient information options. Press the **RUN** button to enter your selection, and advance to the next screen for the next patient information item.
4. After all patient information needed for the Risk Assessment Program has been entered, the result will be displayed like this:

```
10-Year CHD  
Risk=13%
```

5. Press the **DATA** button to move to the next screen. If print option in the Configuration Menu has been set to “On,” the screen will display:

```
Print?  
RUN=yes, STOP=no
```

---

If print option in the Configuration Menu has been set to "Off," the screen will display:

End of Data Info

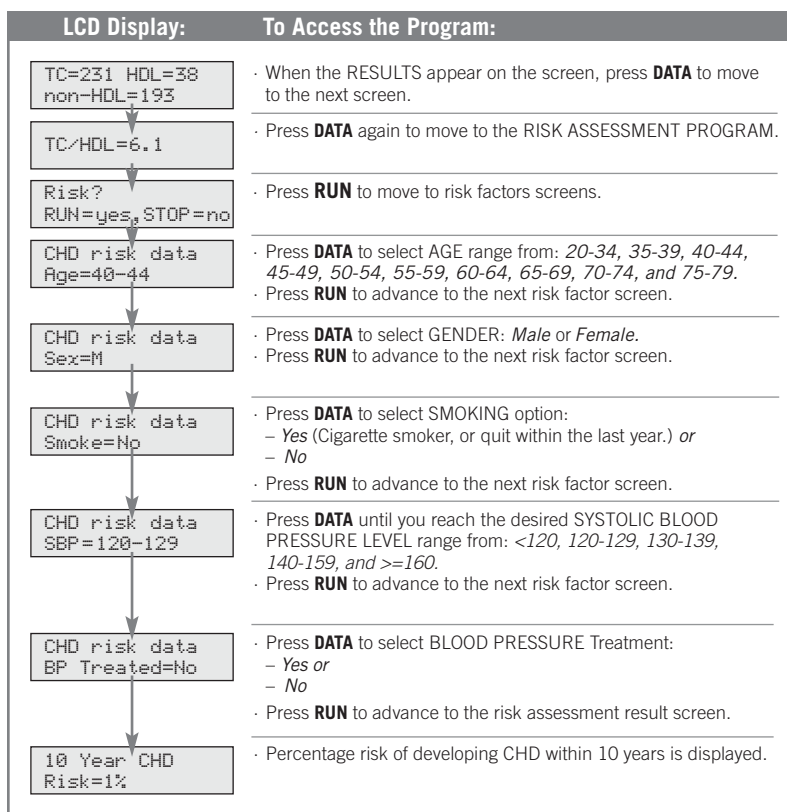
6. If print option in the Configuration Menu has been set to "On" and the answer to "Print?" is "yes," the Risk Assessment result will be printed along with the regular test results. If the answer to "Print?" is "no," only regular test results will be printed.

You may exit the Risk Assessment Option by pressing **STOP** at any time during the program. The result will be N/A.



## Risk Assessment Flowchart

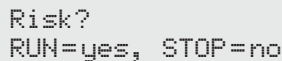
The Analyzer allows you to access a Coronary Heart Disease Risk Assessment Program based on the Framingham Study. To access this program, you must first run a patient sample on a test cassette that includes both TC (total cholesterol) and HDL cholesterol.



## Risk Assessment Modeling

After running a test and performing an initial risk assessment, the Cholestech LDX Risk Assessment Program allows you to change the information in the file to see how these changes will impact the patient's risk of developing heart disease. This helps to illustrate the effect that lifestyle changes can have. Only manually entered items can be modified.

1. Recall the patient's test results by pressing **DATA**.
2. Press the **DATA** button until the Risk Assessment Program screen appears. The screen will display:



```
Risk?  
RUN=yes, STOP=no
```

3. Press the **RUN** button to advance to the risk factor you wish to modify. Follow the same instructions for performing a CHD risk assessment.
4. When finished, the new percentage risk of developing coronary heart disease (providing the patient makes the identified changes) will be displayed.
5. To exit the Risk Assessment Program, press **STOP**.

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## Troubleshooting & Maintenance

### Maintenance and Cleaning

**IMPORTANT: Unplug Analyzer prior to cleaning.**

No maintenance is required other than routine cleaning.

- Clean the outside of the Cholestech LDX Analyzer case with a clean, damp cloth. If necessary, a mild detergent or disinfectant (such as a 5% bleach solution) may be used. **Do not** immerse the Analyzer in water or other cleaning fluid. **Do not** use any abrasive cleanser.
- When necessary, clean inside the cassette drawer with a cotton swab moistened with water, a 70% isopropyl alcohol solution, a 5% bleach solution, or disinfectant. Dry with a second (unused) cotton swab.



### Precautions and Warnings

#### Cholestech LDX Analyzer Precautions and Warnings

- Always press **STOP**. Make sure that the cassette drawer is closed and the screen is blank before unplugging the power supply.
  - Do not remove the ROM pack while the Analyzer is plugged in.
  - Do not allow any liquid, except the sample in a cassette, inside the Analyzer case. If a liquid is spilled on the Analyzer, unplug the power supply and call Cholestech Technical Service at once.
-

- The Analyzer drawer must be left empty when not in use. Do not store cassettes in the Analyzer.
- The Analyzer must be handled carefully to avoid damage when moving from site to site. Carry only one Analyzer in a Cholestech LDX Carrying Case. Do not use the Cholestech LDX Carrying Case to ship the Analyzer. Do not use the Cholestech LDX Carrying Case for air travel as checked baggage. The Analyzer should be shipped in its original box.
- There are no user adjustments in the Analyzer. Do not remove the cover of the Analyzer. This will void the warranty agreement.
- Do not attach any printer or computer to the Analyzer unless using the cable recommended by Cholestech.
- Keep fingers clear of the cassette drawer when it moves in or out of the Analyzer.
- Protect cassettes from magnetic fields that could damage the magnetic stripe (e.g., magnetic stirrer).
- Refer to the package insert that accompanies Cholestech test cassettes for precautions specific for testing with each cassette.

## Corrective Action

| Error Message                         | Problem   | Action to Take   |
|---------------------------------------|---|--|
| WARN 1                                | The Analyzer is in an environment outside its proper temperature range.                   | Move the Analyzer to another location, or wait until the current location reaches acceptable temperature.  |
| WARN 3                                | There is a large difference between two readings that are used to calculate a mean value. | Repeat the test with a new cassette.   |
| WARN 7                                | Kinetic reaction for ALT & AST was not linear.  | Repeat the test with a new cassette.   |
| A/D Error                             | Internal hardware problem.  | Disconnect/Reconnect Analyzer from power supply. If message reappears, call Technical Service.   |
| Bad Checksum                          | Indicates a defective ROM pack.   | Unplug the Analyzer. Remove ROM pack and install a ROM pack from an Analyzer that is functional. If Analyzer is functional with the ROM pack, then the problem is the ROM pack and it will have to be replaced. Call Cholestech Technical Service.   |
| Calibration Fail<br>Call Tech Service | An electrical problem occurred, or the Analyzer lost its optical calibration information. | Disconnect/Reconnect Analyzer from power supply. If message reappears, call Technical Service.   |
| Data file empty                       | This is a normal message that appears:  | <ol style="list-style-type: none"> <li>1. When the optics check has been run and <b>DATA</b> button is pushed.</li> <li>2. A cassette has been run, the power supply has been unplugged from the Analyzer, and <b>DATA</b> button is pushed.</li> <li>3. When an error message occurs, i.e., "Used Cassette," and <b>DATA</b> button is pushed.</li> </ol> |
| End of data info                      | This is a normal message that appears:  | <ol style="list-style-type: none"> <li>1. Framingham risk is off and <b>DATA</b> button is pushed twice after results appear.</li> <li>2. Framingham risk is on and the <b>STOP</b> button is pushed when "Risk? – RUN=yes, STOP=no" appears.</li> </ol>   |
| Expired Cassette                      | Cassette expiration date, month has been reached.   | Check calendar in the Analyzer to make sure it is set correctly. Check expiration date on cassette pouch or box.   |
| Low Battery                           | Internal battery voltage is too low.  | Call Technical Service. Internal battery is not user serviceable.  |
| Mag Read Error<br>See User Manual     | Unable to read magnetic stripe on the cassette.   | <ol style="list-style-type: none"> <li>1. Wipe magnetic stripe with a soft tissue and restart test. If second test fails, repeat test using a new cassette.</li> <li>2. Check cassette position; magnetic stripe must be on the right.</li> <li>3. If message reappears, call Technical Service.</li> </ol>  |
|                                       | <b>RUN</b> button pushed without cassette in drawer.                                      | Place cassette in drawer before pushing <b>RUN</b> button.   |

**Note:** Do not try to run a cassette if you have been troubleshooting a problem with it for more than 30 seconds. Evaporation of sample may cause inaccurate results.

| Error Message  | Problem   | Action to Take  |
|--|---|---|
| Optics Test Fail<br>See User Manual                          | A problem with the optical system of the Analyzer or a faulty Optics Check Cassette.  | Repeat optics check with another Optics Check Cassette. If the message reappears, call Cholestech Technical Service. The Analyzer will now be deactivated.    |
| Reaction Did Not Occur<br>(nnnn)                             | Insufficient sample volume was applied to the cassette due to air bubbles or incompletely filled capillary tube or pipetting error. | 1. Repeat test with a new cassette and new fingerstick sample.<br>2. Repeat test with a new pipette tip and cassette. Be sure pipette tip is firmly in place. |
|  | Insufficient sample volume reached reaction pads due to high hematocrit of sample.  | Repeat test with a new cassette and new fingerstick sample. If message reappears, test patient by alternate method.   |
|  | Improper sample collection: Sample clotted because it was left in capillary tube too long.  | Repeat test with a new cassette and new fingerstick sample. Pay close attention to proper technique.  |
|  | Improper sample collection: Finger was milked to obtain sample, or capillary tube was filled too slowly.                            | Repeat test with a new cassette and new fingerstick sample. Pay close attention to proper technique.  |
|  | The cassette is malfunctioning.   | Repeat test with a new cassette.  |
| Selftest Fail  | Analyzer has lost internal memory; temperature malfunction or hardware problem.   | Disconnect/Reconnect Analyzer from power supply. If message reappears, call Cholestech Technical Service.   |
| Temp Too High<br>See User Manual or Temperature Out of Range | The Analyzer is in an environment outside its proper temperature range.   | Move the Analyzer to another location. When it reaches acceptable temperature, it will again become operable.   |
| Too Much Light<br>See User Manual                            | The Analyzer is in an environment with excessively bright light.  | Move the Analyzer to a location with less light. When light level is acceptable, it will again become operable.   |
| Tray Timeout<br>See User Manual                              | The cassette is jammed in the tray.   | Press <b>RUN</b> ; the drawer will come out. Replace the cassette flat in the drawer and press <b>RUN</b> button.   |
|  | The microprocessor is confused because the buttons were pressed too quickly.  | Disconnect/Reconnect Analyzer from power supply. Repeat test with a new cassette. If message reappears, call Technical Service.                               |
| Used Cassette<br>(nnnn)                                      | A previously used cassette has been placed in the Analyzer.   | Repeat test with a new cassette. Dispose of used cassette appropriately.  |
|  | The cassette was placed incorrectly.  | Repeat test with a new cassette. Call Technical Service if message reappears.   |
|  | The cassette is malfunctioning.   | Repeat test with a new cassette.  |

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## *General Specifications:*

### *Normal Environmental Conditions*

#### **Operating Voltage**

- +9 volt DC at 1 amp

#### **Environmental Conditions**

- Indoor use
- Altitude up to 6,561 feet (2,000 meters)
- Temperature 68 – 87°F (20 – 31°C)
- Relative humidity 80% for temperature up to 87°F (31°C), decreasing linearly to 50% relative humidity at 104°F (40°C)
- Pollution degree: Class 2

If the equipment (Cholestech LDX Analyzer) is used in a manner not specified by the manufacturer (Cholestech), the protection provided by the equipment may be impaired.



*In vitro* diagnostic medical device



Biological risks



Read User Manual before using  
Cholestech LDX Analyzer

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## *Notes*

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## System User Manual



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